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CONTRACTING ORGANIZATION: Mount Sinai School of Medicine
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The goals of this project are to develop a computerized decision analysis model concerning the risks and benefits of hormone replacement therapy for breast cancer survivors.

During the first year, we updated our literature search and review and found numerous studies relevant to our question. We developed a pilot instrument to measure patient preferences, but found that this did not provide useful information. We have begun construction of two alternative decision analysis models. During the next year we plan to continue development of the model. Because of the complexities of developing valid instruments for measuring patient preferences (utilities), we have rearranged our budget to permit us to obtain the consultative services of Dr. Albert Wu of John Hopkins University, an authority on measurement of quality of life.

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FOREWORD

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PI Signature 8/19/98 Date

Table of Contents **PAGES**

INTRODUCTION

The benefits and risks of hormone replacement therapy (HRT) for post-menopausal women have been studied extensively, and yet for most women the choice remains one of uncertainty. HRT is widely believed to decrease the future risk of coronary heart disease, osteoporosis, and stroke, but also it is widely believed to increase the future risk of breast and endometrial cancer. The addition of progestin to estrogen is believed to eliminate the increased risk of endometrial cancer, but may also lessen the preventive effect on coronary heart disease risk. HRT is also known to affect serum lipoproteins, sexual function, and urinary function, and it can cause endometrial hyperplasia and other adverse effects, and may require invasive monitoring procedures. Although the American College of Physicians and others have studied HRT and provide guidelines for women with a variety of risk factors, none of the recommendations apply to women with a history of breast cancer. In addition, the guidelines apply to population groups and not to individuals. Any individual may value a health state, an intervention, or the future risk of an illness differently than do others. Personal decisions regarding preventive medicine therefore should reflect these valuations.

It is widely believed that HRT is contraindicated in postmenopausal women who have had breast cancer. However, HRT has not been adequately studied among breast cancer survivors. The detection of early breast cancer has increased dramatically during the last decade accompanied with a rise in five year survival of treated patients, so there are many women who need guidance. There are approximately 182,000 new cases of breast cancer in women in the U.S. per year. Since the majority of these women will have localized disease can expect to survive 20 years or more, they will face risks of vascular and bone disease similar to those without a history of breast cancer. The induction of premature menopause with adjuvant chemotherapy increases the risk of coronary artery disease and osteoporosis among these women. The prohibition of HRT may diminish overall survival and quality of life among breast cancer survivors despite higher risk of endometrial and breast carcinoma with this intervention

Until the results of clinical trials of HRT in breast cancer survivors are available, which will take many years, it will remain uncertain as to whether this population of women should be given HRT. While we await such results, we are developing a decision analysis method utilizing a mathematical model to provide guidance for women with breast cancer as to whether they should take HRT.

BODY

The goals of this project are to develop a computerized decision analysis model concerning the risks and benefits of hormone replacement therapy for breast cancer survivors.

During the first year, we updated our literature search and review and found numerous studies relevant to our question. We developed a pilot instrument to measure patient preferences, but found that this did not provide useful information. We have begun construction of two alternative decision analysis models. During the next year we plan to continue development of the model. Because of the complexities of developing valid instruments for measuring patient preferences (utilities), we have rearranged our budget to permit us to obtain the consultative services of Dr. Albert Wu of John Hopkins University, an authority on measurement of quality of life.

CONCLUSIONS

At this early stage in the project, we have not reached any conclusions.

JOHNS HOPKINS
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July 10, 1998

Henry Sacks, Ph.D., M.D.
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Medicine and Biomathematical Sciences
Director, Thomas C. Chalmers
Clinical Trials Unit
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The Mount Sinai Medical Center
One Gustave L. Levy Place
New York, NY 10029-6574

Dear Henry:

It was good talking to you earlier this week. Dr. Eric Bass and I are very enthusiastic about working with you on your project "Hormone replacement therapy (HRT) for breast cancer survivors". We will take primary responsibility for describing the health utilities of women with early breast cancer, and those without breast cancer, for health states related to HRT.

As we discussed, the work will take place over the next two years, beginning July 1, 1998. Our consulting rate will be $10,000 for each of the two years, divided evenly between Dr. Bass and myself. This is equivalent to approximately 0.035 FTE for each of us. Checks can be made payable to Johns Hopkins, and sent to me. The Tax free ID # is 152 059 5110.

We look forward to a fruitful collaboration!

Best wishes,

Albert

Albert W. Wu, M.D., M.P.H.
Associate Professor
Departments of Health Policy & Management
and Internal Medicine

AWW:jcf

Mount Sinai

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Date: July 1, 1998

GCO Project#95-545CM(X)
Principal Investigator
Henry Sacks, M.D.,Ph.D.

Department of the Army,

Dear Sir/Madam,

The project entitled **Hormonal Replacement Therapy For Breast Cancer Survivors: A Decision Analysis** includes activities involving human subjects. The Institutional Review Board of the Mount Sinai School of Medicine reviewed this project by expedited review in accordance with our assurance to the Department of Health and Human Services **M-1155** and approved it on **7/1/98.**

Sincerely yours,

Joseph S. Eisenman, Ph.D.
Vice-Chairperson
Institutional Review Board

Institutional Review Board Posting

FROM: Shari Melman, Administrator
Institutional Review Board
Annenberg 5-206 Box 1075
Extension 48673

Date: 1 July 1998

95-545 CM (X)
HORMONAL REPLACEMENT THERAPY FOR BREAST CANCER SURVIVORS: A DECISION ANALYSIS
Henry Sacks, M.D., Ph.D.
Approved for the period ending **6/30/99**

No changes may be made to the protocol nor to the consent form without IRB approval. Submit any proposed changes promptly in order to avoid delays. Please indicate the GCO project number on all pages. *When presenting revisions, please submit a memo explaining the changes as well as two copies of the consent form: one copy with all revisions highlighted and a clean copy to be stamped when granted final approval.*

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